Remarks

Status of the Claims

Claims 1, 2 and 5-8 were pending. Claim 2 has been amended to be rewritten in independent form. Claims 51-56 have been added. Support for these amendments can be found throughout the specification. Upon entry of this amendment claims 1, 2, 5-8 and 51-56 will be pending. No new matter has been added.

As an initial matter claim 2 was not rejected in the Office Action dated April 30, 2008. Accordingly, the subject matter of claim 2 appears to be allowable. Applicants respectfully assert that claim 2 now rewritten in independent form, is allowable.

Priority

The Office alleges, that "for the purposes of applying prior art, this application has been afforded an effective filing date of 22 December, 2000" because the other applications to which the present application claims priority, U.S. Serial No. 09/006,678, filed January 13, 1998, and U.S. Provisional Serial No. 60,047,226, filed May 20, 1997, allegedly fail to provide adequate support for the claimed invention. Applicants respectfully disagree.

The Office alleges that the prior filed applications disclose a subset of multiple membrane spanning proteins, virus receptor proteins, and that the description describing these virus receptor proteins does not adequately support, "multiple membrane spanning protein," used in claim 1. The Office alleges that the applications only disclose cellular virus receptor proteins and that "although two of the disclosed cellular virus receptor proteins were also multiple membrane spanning proteins . . . there was no discussion of virus-like particles simply comprising multiple membrane spanning proteins, particularly those that are not necessarily cellular virus receptor proteins." *Office Action*, at 3. The Office also notes that the multiple membrane spanning proteins CXCR2, CXCR3, mu-opoid, and KCNH2 potassium channel protein are not disclosed in either the '226 or the '678 applications. The Office alleges that because "the only discussion in these earlier applications is clearly directed toward cellular virus

receptor proteins" the present application is not entitled to priority to the '226 application or the '678 application. *Id.* Applicants respectfully disagree.

The priority applications adequately describe claim 1 because the descriptions contained in the two priority documents "would immediately convey" to a person skilled in the art that the applicant invented a virus like particle comprising a multiple membrane spanning protein regardless of whether or not the protein is a virus receptor protein. *In re Smythe*, 480 F.2d 1376, 1384 (C.C.P.A. 1973). Whether an application adequately describes an invention requires that the application "reasonably convey to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date." *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123 (Fed. Cir. 2004). Furthermore, to satisfy the written description requirement the specification "need not provide *in heac verba* support for the claimed subject matter at issue." *Lampi Corp. v. American Power Products, Inc.*, 228 F.3d 1365, 1378 (Fed. Cir. 2000).

The Office appears to allege that because claim 1 is broader than embodiments disclosed in the priority specifications the claim is not adequately described in these priority applications. The Office's standard for determining whether an application provides adequate written description is not the proper legal standard. "That a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment." *In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981). In *Rasmussen*, the claim recited the term "adheringly applying" as a general term. *Id.* The court noted that the *Rasmussen* specification described "one method of 'adheringly applying" one layer to another. *Id.* The court held the specification adequately described the claim because "one skilled in the art who read [the] specification would understand that it is unimportant how they layers are adhered so long as they are adhered." *Id.* Here, as in *Rasmussen* where the method described was only an embodiment and not a limiting embodiment, the particles comprising multiple membrane spanning virus receptor proteins, which are a subgenus of multiple membrane spanning proteins, are just one embodiment of the present invention.

The present specification discusses particles that comprise various proteins including multiple membrane spanning proteins, which happen to be virus receptor proteins. Furthermore, the priority applications describe the incorporation of chemokine receptors generally and not all

chemokine receptors are virus receptor proteins. For example, in the '226 and '678 applications there are numerous textual references to multiple membrane spanning proteins being incorporated into particles. Specifically, in the '678 application the specification states that the particles can incorporate multiple membrane spanning proteins and then provides specific examples that include chemokine receptors (e.g. CCR5 and CXCR4). (See, '678 specification, p. 4, lines 12-14, p. 16, lines 2-5).

The priority documents also provide adequate written description for claim 1 because the priority documents do not indicate that the multiple membrane spanning protein must be a virus receptor protein. The specification would reasonably convey to the skilled artisan that Applicants were in possession of particles comprising multiple membrane spanning proteins at the time the priority documents were filed. An embodiment, even a preferred embodiment, does not set the bounds of what is adequately described in a disclosure. *See Lampi*, 228 F.3d at 1377-79. In *Lampi*, the defendant argued that the specification did not provide adequate written description to a claim term that encompassed identical half-shells and non-identical half-shells because the patent only described identical half-shells. *Id.* at 1377. In *Lampi*, the court held that the description did adequately describe the generic term and that using a specific embodiment to limit what is adequately described was not proper. *Id.* at 1377-79. In *Lampi*, the court found that there was nothing in the *Lampi* specification that indicated that identical half-shells were "critical to the invention." *Id.* at 1378. Even though the *Lampi* specification only had examples comprising identical half-shells this fact did not "compel the conclusion that the written description of the [patent] is so narrowly tailored as to preclude Lampi from claiming" using a generic term that includes non-identical half-shells. *Id.* at 1378. The court explained that the embodiments were "merely a 'practical example' of the invention" and the embodiments do not limit the description. *Id.* Accordingly, the court held that one of skill in the art would have understood that Applicants were in possession of the claimed invention. *See Id.*

Here, the situation is the same as in *Lampi*. The priority documents describe particles comprising proteins. Specifically, the priority documents describe a "practical example" of the particles, which are particles comprising multiple membrane spanning proteins. In one embodiment, the multiple membrane spanning proteins also happen to be virus receptor proteins.

However, just as in *Lampi*, there is nothing in the present application's priority documents that indicate that the multiple membrane spanning protein being a virus receptor protein is "critical to the invention." In contrast, the priority documents describe generally that proteins can be incorporated into the particles. For example, the '678 application states

> Another example of making the enveloped virus vector of the invention further comprises providing an additional component to the producer cell, whereby, upon formation of the enveloped virus vector, the enveloped virus vector comprises the additional component. The additional component may be any molecule which can be provided to the cytoplasm or the membrane of the producer cell.

('678 specification, p. 18 lines 4-8). The specification further emphasizes that the particle can be produced with a component when the component is "provided directly to the membrane . . . of the producer cell." ('678 specification p. 18, lines 24-25). This component can be any molecule including a protein, which when viewed in context of the examples can be a generic multiple membrane spanning protein. The specification also describes particles comprising generic test proteins. The definition of a test protein provides that the test protein can be any protein, preferably a membrane protein, and is not limited to only a cellular virus receptor protein as the Office alleges. (See '678 application, p. 28, lines 5-6, p. 35, line 13). The specification, therefore, clearly conveys to one of skill in the art that rather than the virus receptor protein being critical to the invention the particle comprising a virus receptor protein is just one embodiment of the present invention. The skilled artisan would understand from the examples that describe particles comprising multiple membrane spanning proteins that Applicants were in possession of claim 1 when the priority documents were filed.

The '226 application also provides adequate support to show possession of claim 1 when the '226 application was filed. On page 3 of the '226 application, first full paragraph, the specification states that "proteins may be incorporated into the envelope of the [particle] . . . such as, for example, chemokine receptors." This statement does not indicate that the protein must be a virus receptor protein as the Office appears to indicate. One of skill in the art would know that the chemokine receptor is a multiple membrane spanning protein and, thus, would understand that applicants were in possession of particles comprising multiple membrane spanning proteins

as claimed in claim 1. As stated above, not all chemokine receptors are virus receptor proteins something that one of skill in the art would understand and appreciate. On page 8, second full paragraph of the '226 application and throughout the provisional application, the application discusses the role of multiple membrane spanning proteins (e.g. seven transmembrane-spanning G-protein coupled receptors) and describes particles comprising the same. As discussed above, particles comprising a multiple membrane spanning protein, which is also a viral receptor protein, is one embodiment of the invention but does not limit what is adequately described.

One of skill in the art reading the present specification would clearly understand that the applicants were describing an invention that encompasses particles comprising generic heterologous multiple membrane spanning proteins and that the applicants chose to direct their examples toward an embodiment of multiple membrane spanning proteins, such as virus receptor proteins. It is well established that the examples do not limit what one of skill in the art would understand the description to encompass. Claims can encompass "different subject matter than is illustrated in the specific embodiments in the specification." *Nazomi v. Arm Holdings*, 403 F.3d 1364, 1369 (Fed. Cir. 2005). The application must be read as a whole to determine if there is adequate support for the generic claim. Based upon the disclosures in the priority applications one of skill in the art would clearly understand that there is adequate support for the generic claim to afford such claims the priority dates of the ''26 and the '678 applications.

One of skill in the art would also understand that Applicants were in possession of claim 1 when the '226 application was filed because of the examples describing different types of multiple membrane spanning proteins that were incorporated into the particles. For example, on page 24 of the '226 application, the specification describes particles comprising MCAT-1, a multiple membrane spanning protein. MCAT-1 and chemokine receptors are multiple membrane spanning proteins with dramatically different functions. MCAT-1 is an amino acid transporter whereas chemokine receptors bind to chemokines to transduce a signal. The common element between MCAT-1 and the chemokine receptors is that they are both multiple membrane spanning proteins. Due to sharing the common characteristic of being a multiple membrane spanning protein one of skill art would clearly understand that Applicants were in possession of the generic claim at the time the application was filed. The fact that the two different types of

multiple membrane spanning proteins were both incorporated is evidence that they were in possession of claim 1 when the application was filed. Since one of skill in the art would expect that particles comprising different types of multiple membrane spanning proteins would perform similarly no further species or embodiments need to be described. *See Bilstad*, 386 F.3d at 1125 (explaining that if the skilled artisan would not be able to tell that different members of the genus would perform similarly then further description of species is required.) Here, Applicants have described particles comprising "radically different types" of proteins (p. 28, lines 17-18 of the '226 application) and, therefore, one of skill in the art would clearly not find that the examples were unpredictable. Accordingly, read in its entirety, the '226 application clearly provides adequate support and written description for claim 1.

Similar to the case here, in *In re Smythe* the court provided an example of where a description providing one specific embodiment would "immediately convey" the more generic term. 480 F.2d at 1384. In *Smythe*, the court described a hypothetical specification disclosing a scale that comprised a "lead weight." The court stated that this description would not preclude a claim using the generic term "weight" because as a whole the disclosure "would immediately convey" to the skilled artisan that the weight could be of any composition. *Id.* Here, as in *Smythe*, the specification read as a whole would immediately convey that the particle comprising a multiple membrane spanning protein can be any multiple membrane spanning protein and not just a multiple membrane spanning protein that is also a virus receptor protein. The Office is attempting to limit what the specification describes based upon the embodiments disclosed, but this is not the proper standard. The proper standard for determining what is adequately disclosed is what the applications would reasonably convey to the skilled artisan to show possession of the invention at the time the applications were filed. For the reasons stated above the '226 and the '678 applications would clearly convey to the skilled artisan that they were in possession of claim 1 at the time the applications were filed.

Accordingly, Applicants have provided adequate written description in both the '226 application and the '678 application and the present application is entitled to claim priority to each. In view of the foregoing, Applicants respectfully request that the effective filing date of

the present application be the filing date of the '226 provisional application and that the Office state that the claim to priority for claim 1 is proper.

Rejections under 35 U.S.C. § 102

Claims 1 and 5-8 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Hoffman et al. Proc. Natl. Acad. Sci. U. S. A., 97(21): 11215-11220. Applicants respectfully disagree.

As discussed above, the present application claims priority to U.S. Application Serial No. 09/006,678, filed January 13, 1998, and U.S. Provisional Application Serial No. 60,047,226, filed May 20, 1997. These applications both predate the Hoffman reference. As discussed above, the priority applications provide adequate support for the pending claims. Therefore, the Hoffman reference is not available as prior art because it was published after the filing dates of these applications. Accordingly, because the priority applications provide adequate support for the claims and the effective filing date of the present application is prior to the publication date of the Hoffman reference Applicants request that the rejection under 35 U.S.C. § 102 be withdrawn.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 102(a) be withdrawn.

Conclusion

Claims 1, 2, 5-8, and 51-56 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7820 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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